REMARKS

Status of the Claims

Claims 35, 37-39, 42-47, 51-52, 55-56, 61-67 and 82-92 are pending; claims 1-34, 36, 40-41, 48-50, 53-54, 57-60 and 68-81 are canceled; claims 93-95 are added; and no claim has been amended.

New claims 93-95 recite the similar subject matter to that of claims 35, 52, and 82, but use the closed transitional phrase, "consisting of." Support for this claim is found, for instance, in examples 6 and 7 of the Specification.

No new matter has been added.

1. Claim Rejections under 35 USC Section 103

The Examiner has rejected claims 35, 37-39, 42-47, 51-52, 55-56, 61-67 and 82-92 as allegedly obvious over Wong et al. (USPN 5,869,079). (Office Action, pages 2-5). Applicants respectfully traverse.

Applicants note that there are two parts to the Examiner's obviousness rejection. In the first part, the Examiner construes the transitional phrase of the pending claims, "consisting essentially of," as not eliminating the possibility of the presently claimed implants containing a release modifier: *i.e.* the Examiner contends that, in the context of the present application, the "consisting essentially of" transitional phrase is open and tantamount to the transitional phrase, "comprising." (Office Action, pages 2-5). In the second part of the obviousness rejection, the Examiner asserts that, even if the transition of the present claims were to exclude the possibility of a release modifier from being contained in the presently claimed implants, the presently claimed implants would still be obvious over Wong et al.

Applicants address each part of the Examiner's obviousness rejection in the following sections.

1.1 Claim Construction

On page 2 of the Office Action, the Examiner dismisses as unconvincing Applicants' interpretation of the transitional phrase, "consisting essentially of," as excluding release modifiers from the presently claimed implants. The Examiner cites to the following portion of M.P.E.P. Section 2111.03 as allegedly supporting her interpretation that the "consisting essentially of" transitional phrase does not exclude release modifiers from the President claimed implants:

> The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original) (Prior art hydraulic fluid required a dispersant which appellants argued was excluded from claims limited to a functional fluid "consisting essentially of" certain components. In finding the claims did not exclude the prior art dispersant, the Court noted that appellants' specification indicated the claimed composition can contain any well-known additive such as a dispersant, and there was no evidence that the presence of a dispersant would materially affect the basic and novel characteristic of the claimed invention. The prior art composition had the same basic and novel characteristics (increased oxidation resistance) as well as additional enhanced detergent and dispersant characteristics.). ... For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, **absent a clear indication in the specification or claims** of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to 'comprising.' See, e.g., *PPG*, "... (Office Action, page 4). (Emphasis added).

But the Examiner misinterprets M.P.E.P. Section 2111.03 and fails to give the teachings of the present Specification its proper evidentiary weight. In particular, the Examiner states:

> "As required by the M.P.E.P., determining what ingredients are eliminated by the phrase 'consisting essentially of' is ascertained by examining the specification. Does the modifier change the material aspects of the claimed invention? Does the specification provide a 'clear indication' as required by PPG in this regard?" (Office Action, page 4). (Emphasis added)

The Examiner misinterprets M.P.E.P. Section 2111.03 by asserting that determining what ingredients are limited by the "consisting essentially of" transitional phrase is ascertained only by examining the specification. In fact, M.P.E.P. Section 2111.03 expressly requires that, under *PPG*, such a determination is ascertained by examining both the specification and the claims.

The Examiner goes on to state that "[t]he first mention of release modulators occurs deep into Applicant's description of the invention, even after the 'shopping list' of antibacterials, antineoplastics, antifungals, antibiotics, etc.," (Office Action, page 4). In making this assertion, the Examiner fails to give the disclosure of the present specification its proper evidentiary weight. In particular, the Examiner appears to be discounting the specification's teachings regarding release modifiers on the grounds that "the first mention of a release modulators occurs deep into Applicant's description of the invention." But Applicants' point out that there is no legal authority which permits disclosure that appears for the first time "deep into" a specification to be given less evidentiary weight simply because of the position in which it resides in the overall context of the specification. This comment by the Examiner is therefore completely irrelevant in the determination of whether or not the transitional phrase, "consisting essentially of," excludes release modifiers from the presently claimed implants. (Applicants further point out that, for similar reasons the "shopping list" language is also wholly irrelevant to the obvious analysis).

The Examiner further notes that Applicant's published paragraph [0064],

> "happens to eliminate the modifier, however, these experiments are also provided in the prior art patent, and no guidance is provided that makes elimination of the release modifier novel other than what is provided by Applicant' s argument only after the prior art rejection in view of Wong." (Office Action, pages 4-5).

By making this assertion, the Examiner once again fails to give the disclosure of the present specification its proper evidentiary weight. In particular, the specification does not simply "happen" to disclose the effects that eliminating release modifiers have on the presently claimed implants in a meaningless way, as the Examiner appears to imply with the "happen" language. Rather, the application states that release modifiers indeed can be excluded from implants within the scope of the present application. Moreover, Examples 6 and 7 and corresponding Tables 6 and 7 clearly show the drug release profiles of the presently claimed implants: *i.e.* implants which do not contain release modifiers. Examples 6 and 7 show that at least about 20% and 30% of the active agent of the implants is released within about 20 days *in vitro*, respectively. Applicants submit that the presently claimed implants are novel and nonobvious over those taught by the cited prior art for least their drug release profiles which are, of course, material limitations of the presently claimed implants. (Applicants present, in section 1.2 below, a full discussion regarding the nonobviousness of the presently claimed implants over the cited prior art).

As is clear from the foregoing discussion, both the instant specification and claims provide a clear indication of the basic novel and nonobvious characteristics of the claimed implants. It follows that the transitional phrase, "consisting essentially of," is not tantamount to "comprising," and indeed excludes the possibility that the presently claimed implants contain release modifiers.

1.2 The Prior Art

On page 5 of the Office Action, the Examiner contends that, even if the claims exclude release modifiers from the presently claimed implants, the claimed implants would be obvious over Wong et al. But the Examiner' s obviousness analysis is improper and inaccurate, which leads the Examiner to make the erroneous determination that the presently claimed implants are obvious over Wong et al.

The teachings of Wong et al.: Wong et al. teaches manufacturing of a drug delivery system without a release modulator in Example 1. (Column 8, lines 20-22). The Wong release-modulator-free drug delivery system comprises dexamethasone and PLGA in a 50:50 (w:w) ratio, was extruded from a 20 gauge orifice and cut into implants of 100-120 micrograms. (Column 8, lines 23-32). Wong et al. discloses the drug release profiles of these release-modulator-free implants in Figure 1A, which clearly shows that those implants have a drug release profile in which just under 10% of the dexamethasone steroidal anti-inflammatory agent is released after 20 days. Moreover, the Wong release-modulator-free implants did not release 20% of their anti-inflammatory agent until after 25 days *in vitro* or 30% of their anti-inflammatory agent until after 29 days *in vitro*.

Wong et al. further discloses that the size and form of an implant can be used to control its rate of drug release, and that larger implants may have a slower release rate, depending on their surface-to-mass ratio. (Column 7, lines 53-55). Applicants submit that it is well-known in the art that the surface-to-mass ratio of filamentous objects of the same composition and proportional shape decreases with increasing weight.

Wong et al. fails to teach the presently claimed implants: Applicants point out that the presently claimed implants release at least about 20% or 30% of their steroidal anti-inflammatory agents within about 20 days in vitro. This release profile is, of course, significantly and substantially outside the above-discussed drug release profiles for the release modulator-free

implants taught by Wong et al. For at least this reason, Wong et al. fails to teach the presently claimed implants.

Wong et al. teaches away from the presently claimed implants: Applicants point out that the difference between the implants taught by Wong et al. in Example 1/Figure 1a is that the instantly claimed implants are larger and mass than the release-modulator-free implants taught by Wong et al.. In particular, Applicants' claimed implants have a mass of between 500 and 1100 mcg; whereas the implants taught by Wong et al. have a mass of between 100 and 120 mcg. Both the presently claimed implants and those taught by a Wong et al. have the same composition and shape. It follows that a person of skill in the art, upon reading the above-discussed disclosure by Wong et al., would believe that the presently claimed implants should release their dexamethasone anti-inflammatory agent more slowly than the smaller implants taught by a Wong et al. But, as discussed above, the presently claimed larger implants in fact have a faster release rate vis-à-vis the active agent: *i.e.* the presently-claimed; larger implants release dexamethasone at a rate that is 2-3x faster than the smaller implants taught by Wong et al. Accordingly, Wong et al. strongly teaches away from the presently claimed implants having the presently claimed drug release profiles.

The Examiner has failed to establish a *prima facie* case of obviousness over Wong et al.: For at least the foregoing reasons, Applicants submit that Wong et al. both fails to teach the presently claimed implants and teaches away from them. The Examiner has therefore failed to establish *prima facie* obviousness against the instantly claimed implants over Wong et al., and Applicants therefor respectfully request reconsideration and withdrawal of the instant obviousness rejection.

The Examiner's obvious analysis is improper:

Moreover, Applicants point out that is well established that the use of *per se* rules is prohibited in an obviousness rejection. In particular, the Federal Circuit has held in *In re Ochiai* that the use of per se rules flouts section 103 and the fundamental case law applying it, *Graham* and its

progeny. *Per se* rules that eliminate the need for fact-specific analysis of claims and prior art may be administratively convenient, but reliance on *per se* rules of obviousness is legally incorrect and must cease. 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995). Any such administrative convenience is simply inconsistent with section 103, which, according to *Graham* and its progeny, entitles an Applicant to issuance of an otherwise proper patent unless the PTO establishes that the invention as claimed in the application is obvious over cited prior art, based on the specific comparison of that prior art with claim limitations. *In re Ochiai*, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995).

Applicants point out that, in making the obviousness rejection, the Examiner entirely fails to analyze the teachings of the prior art reference of record, Wong et al. Instead, the Examiner broadly speculates that "the weight of the device, the agent release percentages after certain time periods, the weight percent of the device, etc." are routine considerations in designing implants made by ocular care physicians during the course of an ordinary working day. (Office Action, page 5). The Examiner further entirely fails to take into account the above-discussed ramifications of Wong et al. on the grounds that "the release rate of the implant is highly dependent upon the placement of the device." (Office Action, page 5). Here, the Examiner entirely fails to take into account the fact that the claims specify that the implant is placed in the vitreous of the eye, and not random locations throughout the eye as implied by the Examiner.

Because the Examiner has, as discussed above, failed to engage in the requisite comparison between the disclosure of the prior art and the claimed invention, the Examiner is effectively applying obviousness as a per se rule, in violation of *In re Ochiai*. Although the Examiner has undoubtedly achieved administrative efficiency by taking this approach (*e.g.* the Examiner dismisses the presently claimed invention as obvious over Wong et al. in a mere single paragraph), the Examiner's broadly speculative and superficial obviousness analysis has led to the wrong determination, in violation of the requirements of *Graham* and its progeny.

For these reasons as well, Applicants respectfully submit that the Examiner has failed to carry

the burden of establishing a *prima facie* case of obviousness against the presently claimed implants.

2. Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request immediate allows of the application, the claims of which define subject matter that meets all statutory patentability requirements.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicants respectfully petitions for a three (3) month extension of time for filing a reply in connection with the present application, and the required fee of is attached hereto.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Leonard R. Svensson Reg. No. 30,330 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

Dated: December 11, 2007

Respectfully submitted,

By _____

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